

Consistency of use of plant stanol ester margarine in Finland

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Abstract

Objective: The aims of this study were to investigate the consistency of use of plant stanol ester margarine and to characterise consistent and inconsistent users.

Design: A cohort of plant stanol ester margarine users was established based on 14 national surveys conducted by the National Public Health Institute in Finland between 1996 and 1999. A follow-up study questionnaire was developed and sent to 1294 users in 2000.

Setting: Subjects who reported using plant stanol ester margarine in both the original survey and the follow-up study were classified as consistent users, and the rest as inconsistent users.

Subjects: The study population consisted of 1094 subjects aged 18–87 years, 590 men and 504 women.

Results: There were 357 (33%) consistent and 737 (67%) inconsistent users of plant stanol ester margarine in the study population. Consistent users were more likely to be men and to have a higher household income than inconsistent users. Both consistent and inconsistent users were predominantly middle-aged persons with a healthy lifestyle and diet as well as a history of cardiovascular disease. Healthfulness was the main factor affecting bread spread choice among 94% of the consistent users and 59% of the inconsistent users.

Conclusions: The use of plant stanol ester margarine is more often inconsistent than consistent. There is nevertheless a relatively large subgroup of long-term users of plant stanol ester margarine. It is important to examine the health effects especially among these regular users.

Keywords
Consistency
Plant stanol
Margarine
Finland

Functional foods are foods that have been shown to have beneficial health effects beyond adequate nutritional effects¹. During the past decade, there has been increasing availability and use of functional food products worldwide. Hence, there is a need for post-marketing research and surveillance of functional food use patterns and health effects^{2–4}.

The plant stanol ester margarine Benecol® (Raisio Group, Raisio, Finland) is a functional food that effectively lowers serum total and low-density lipoprotein cholesterol according to several interventions^{5,6}, and is recommended by the Finnish Society for Internal Medicine for the primary and secondary prevention of coronary heart disease⁷. A longitudinal study of the plant stanol ester margarine was launched at the National Public Health Institute in Finland in 1998 in order to evaluate the so far unknown potential health effects of long-term use of plant stanol ester margarine.

Our previous study showed that plant stanol ester margarine users are often elderly persons, many of whom have a history of cardiovascular disease⁸. The aims of this study were to investigate the consistency of use of plant stanol ester margarine and to characterise consistent and inconsistent users. This information is necessary in future studies of the possible health effects, both beneficial and adverse, of long-term use of plant stanol ester margarine.

Methods

A cohort of users of plant stanol ester margarine was established based on 14 national surveys conducted by the National Public Health Institute in Finland between 1996 and 1999. The main surveys were the annual Finnish Adult Health Behaviour Surveys⁹ and the Chronic Disease Risk Factor Survey (Finrisk)¹⁰. In each survey, sampling was either purely random or stratified random with respect to

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age and geographical area, and subjects completed mailed questionnaires concerning their health and lifestyle. Participation rates in the surveys varied from 64 to 79%.

There were 1307 plant stanol ester margarine users aged 15–84 years in the cohort, which was 3.4% of the total number of respondents who gave non-missing information on the bread spread question in the 14 surveys ($n = 38\,552$). They had been identified using the following question in the survey questionnaire: 'What type of fat do you usually use on bread?' Choices were no fat at all, low-fat spread, soft margarine, butter–oil mixture, butter, and plant stanol ester margarine Benecol. The plant stanol ester margarine Benecol was the only plant sterol margarine available to consumers in Finland during the time the surveys were conducted.

A follow-up study questionnaire was developed in order to update the information gathered in the original surveys and to study the consistency of use of the plant stanol ester margarine. Variables that were updated covered socio-economic background, health status, medication, smoking, diet, use of alcohol, height, weight and physical activity. The same question on bread spread was used in the follow-up study as in the original survey to identify users of plant stanol ester margarine with the addition of the response option 'plant sterol spread', which had recently been launched on the Finnish market.

New dietary questions were developed such as the type and amount of bread spread used during the past 5 years and the main factor affecting bread spread choice. A picture from a portion size picture booklet describing the amount of spread on bread was also included to improve the validity of the estimation¹¹. In addition to the plant sterol margarines, an unripened cheese product with plant stanol ester was on the Finnish market at that time and a question concerning its use was thus added to the questionnaire. The questionnaire was tested among 19 employees of the National Public Health Institute and 40 customers of a store in Helsinki, Finland. Questions were well answered and not considered too difficult.

Addresses of the subjects were updated through the Population Register Centre of Finland. Questionnaires were sent to living users of plant stanol ester margarine who had a permanent address ($n = 1294$) in October 2000. Two reminders were sent to non-respondents at 3–4 week intervals. Written consent concerning the use of questionnaire responses and future linkage of the cohort to health outcome registers was required.

Overall, 1122 persons responded to the follow-up study questionnaire (87%). Three subjects declined to give consent and were excluded. Six subjects, who gave permission to use questionnaire responses but not registry data, were included. There were 12 subjects who provided questionnaire responses but failed to provide consent despite reminders. They were included in this study because completing and returning the questionnaire was considered permission to use the questionnaire data.

Subjects with missing information on the bread spread question ($n = 25$) were excluded from the analyses. The final study population thus consisted of 1094 subjects aged 18–87 years, 590 men and 504 women.

Subjects who reported using plant stanol ester margarine in both the original survey and the follow-up study were classified as consistent users. Subjects who reported using plant stanol ester margarine in the original survey but not in the follow-up study were classified as inconsistent users. The time interval between completion of the original survey questionnaire and the follow-up study questionnaire ranged from 1.5 to 4.5 years.

Consistent and inconsistent users were compared with respect to sex, age, socio-economic background, self-reported health, bread spread use, diet, body mass index and physical activity. Unadjusted prevalence percentages were computed. The Chi-square test was applied. Data management and statistical analysis were performed using the SAS System (version 6.12)¹².

Results

There were 357 (33%) consistent and 737 (67%) inconsistent users of plant stanol ester margarine in the study population. Consistent users were more likely to be men and to have higher household income than users (Table 1). Both the consistent and the inconsistent users were predominantly middle-aged (mean age 62 and 61 years, respectively), married and retired citizens with middle or high education (mean years of education 12 and 11, respectively).

More than half of both consistent and inconsistent users of plant stanol ester margarine reported having a cardiovascular disease and having had their blood cholesterol measured during the past 12 months (Table 2). Of the consistent users, 78% reported a diagnosis of high or elevated blood cholesterol, and 83% of those with high cholesterol had received dietary counselling for lowering of blood cholesterol, compared with slightly lower proportions (72% and 78%, respectively) among inconsistent users. More than half (55%) of both the consistent and inconsistent users perceived their health as good.

The inconsistent users had changed their bread spread type from plant stanol ester margarine to low-fat spread (54%), no fat at all (14%), soft margarine (13%), butter–oil mixture (10%), plant sterol spread (7%) or butter (2%) (Table 3). Consistent users used, on average, 24 g of plant stanol ester margarine on their bread daily, compared with 21 g of bread spread among inconsistent users. Almost all (98%) consistent users had used plant stanol ester margarine for at least 2 years, while one-third had used it for 5 years. Healthfulness was the main factor affecting bread spread choice among 94% of the consistent users and 59% of the inconsistent users. Of the consistent users, 23% reported using the unripened cheese product with

Table 1 Sex, age and socio-economic background among consistent and inconsistent users of plant stanol ester margarine

	Consistent users		Inconsistent users		Total		Consistent vs. inconsistent users	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	χ^2	<i>P</i> -value
Sex								
Men	225	63	365	50	590	54	18	0.001
Women	132	37	372	50	504	46		
Total	357	100	737	100	1094	100		
10-year age group								
18–24 years	0	0	7	1	7	1	12	0.058
25–34 years	1	0	10	1	11	1		
35–44 years	11	3	41	6	52	5		
45–54 years	79	22	146	20	225	21		
55–64 years	103	29	229	31	332	30		
65–74 years	124	35	220	30	344	31		
75–87 years	39	11	84	11	123	11		
Total	357	100	737	100	1094	100		
Education								
1–9 years	142	40	283	39	425	40	5.1	0.077
10–12 years	72	21	190	26	262	24		
13 years or more	139	39	248	35	387	36		
Total	353	100	721	100	1074	100		
Marital status								
Married, cohabiting	282	79	553	75	835	77	1.8	0.18
Single	75	21	181	25	256	23		
Total	357	100	734	100	1091	100		
Employment status								
Unemployed	9	3	30	4	39	3	1.7	0.42
Employed	138	39	288	40	426	40		
Retired	202	58	406	56	608	57		
Total	349	100	724	100	1073	100		
Household income								
Low	96	27	252	36	348	33	17	0.001
Middle	117	34	257	37	374	36		
High	136	39	186	27	322	31		
Total	349	100	695	100	1044	100		

Table 2 Self-reported health among consistent and inconsistent users of plant stanol ester margarine

	Consistent users		Inconsistent users		Total		Consistent vs. inconsistent users	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	χ^2	<i>P</i> -value
Cardiovascular disease								
Yes	195	55	407	55	602	55	0.035	0.85
No or missing	162	45	330	45	492	45		
Total	357	100	737	100	1094	100		
Blood cholesterol measured during past 12 months								
Yes	200	57	380	52	580	54	2.4	0.12
No	149	43	347	48	496	46		
Total	349	100	727	100	1076	100		
High or elevated blood cholesterol diagnosed ever								
Yes	272	78	517	72	789	74	5.0	0.025
No	77	22	206	28	283	26		
Total	349	100	723	100	1072	100		
Dietary counselling for lowering of blood cholesterol received*								
Yes	259	83	465	78	724	79	4.2	0.041
No	52	17	135	22	187	21		
Total	311	100	600	100	911	100		
Self-perceived health								
Good	191	55	400	55	591	55	2.0	0.37
Average	134	38	252	35	386	36		
Poor	26	7	69	10	95	9		
Total	351	100	721	100	1072	100		

* In the case that high blood cholesterol was diagnosed.

Table 3 Bread spread use among consistent and inconsistent users of plant stanol ester margarine

	Consistent users		Inconsistent users		Total		Consistent vs. inconsistent users	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	χ^2	<i>P</i> -value
Current bread spread choice								
No fat at all	0	0	101	14	101	9	1094	0.001
Low-fat spread	0	0	396	54	396	36		
Soft margarine	0	0	95	13	95	9		
Butter–oil mixture	0	0	74	10	74	7		
Butter	0	0	19	2	19	2		
Plant stanol ester margarine	357	100	0	0	357	32		
Plant sterol spread	0	0	52	7	52	5		
Total	357	100	737	100	1094	100		
Daily amount of spread on bread (g)*								
< 20	148	43	403	57	551	52	18	0.001
20–25	84	24	124	17	208	20		
> 25	113	33	182	26	295	28		
Total	345	100	709	100	1054	100		
Duration of plant stanol ester margarine use (years)†								
1	4	2	64	37	68	14	144	0.001
2	67	22	52	30	119	25		
3	95	32	35	21	130	28		
4	34	11	9	5	43	9		
5	100	33	11	7	111	24		
Total	300	100	171	100	471	100		
Main factor affecting bread spread choice								
Price	1	0	29	4	30	3	146	0.001
Taste	9	3	144	20	153	15		
Healthfulness	327	94	416	59	743	71		
Availability	1	0	7	1	8	1		
Offers in shop	2	1	13	2	15	1		
Other	7	2	19	3	26	2		
No fat on bread	0	0	76	11	76	7		
Total	347	100	704	100	1051	100		

* Amount of spread on one slice of bread estimated using a picture from a portion size picture booklet.

† Between the years 1996 and 2000.

plant stanol ester 6–7 days per week, compared with 12% of the inconsistent users.

Diet could objectively be regarded as healthy among most of the consistent (70%) and inconsistent (61%) users (Table 4). Still higher proportions of consistent (86%) and inconsistent (82%) users perceived their own diets as healthy. Both the consistent and inconsistent users reported to have consumed on average 6 alcoholic units during the past 7 days, while one-third had not consumed any alcohol during that time. Body mass index (mean 26 kg m^{-2}) and leisure-time physical activity were similar among consistent and inconsistent users.

Discussion

Plant stanol ester margarine has been a major innovation in the field of functional foods. The type of dietary fat has a critical influence on blood lipid levels, and consequently on cardiovascular risk^{5,6,13}. In addition to studies of efficacy and safety, post-marketing surveillance studies provide valuable additional information regarding the use patterns of functional foods.

According to our study, consistent and inconsistent users of plant stanol ester margarine share several characteristics. They are predominantly middle-aged persons with a

healthy lifestyle and diet. Among consistent users, men and persons with a high household income are relatively more represented compared with inconsistent users.

By the time of the follow-up study, there were two plant sterol margarines on the Finnish market: the plant stanol ester margarine Benecol (60% and 32% fat) and the plant sterol spread Becel pro.activ™ (35% fat). The plant stanol ester margarine was introduced to the Finnish market in November 1995. Plant sterol spread was launched 2 months before the follow-up study questionnaires were sent. Plant stanol ester margarine and plant sterol spread are sold as ordinary foods in Finland and their marketing is regulated by legislation. Both products cost three to five times more than other margarines. Our study suggests that price has little influence on bread spread choice among plant stanol ester margarine users.

People who use plant stanol ester margarine seem to have problems with blood cholesterol levels and a history of cardiovascular disease. Therefore, it is likely that they use plant stanol ester margarine in order to control blood cholesterol levels through dietary practices. Indeed, the consistent users in our study overwhelmingly regarded healthfulness as the main factor affecting bread spread choice. Most of them had also received dietary counselling for lowering of blood cholesterol.

Table 4 Diet, body mass index and physical activity among consistent and inconsistent users of plant stanol ester margarine

	Consistent users		Inconsistent users		Total		Consistent vs. inconsistent users	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	χ^2	<i>P</i> -value
Diet*								
Healthy	236	70	418	61	654	64	7.9	0.005
Unhealthy	99	30	262	39	361	36		
Total	335	100	680	100	1015	100		
Self-perceived diet								
Healthy	303	86	594	82	897	83	3.0	0.23
Average	46	13	119	16	165	15		
Unhealthy	5	1	16	2	21	2		
Total	354	100	729	100	1083	100		
Use of alcohol†								
No units	102	29	221	31	323	31	1.5	0.47
1–5 units	115	33	249	35	364	34		
6 units or more	132	38	242	34	374	35		
Total	349	100	712	100	1061	100		
Body mass index (kg m ⁻²)‡								
< 25	141	40	280	39	421	39	0.13	0.94
25–30	172	48	352	48	524	48		
> 30	44	12	94	13	138	13		
Total	357	100	726	100	1083	100		
Leisure-time physical activity								
Often	266	77	525	74	791	75	1.7	0.43
Some	58	17	143	20	201	19		
Seldom	23	6	46	6	69	6		
Total	347	100	714	100	1061	100		

* Healthy diet includes at least three of following: daily use of vegetables, avoidance of fatty milk, use of margarine or no spread on bread, use of bread more than 5 slices per day.

† Number of alcoholic units (120 ml wine, 40 ml spirits or one 330 ml bottle of beer, long drink or cider) during the past 7 days.

‡ Self-reported height and weight.

Similarly, healthfulness is an important factor affecting bread spread choice among inconsistent users. This was reflected by the fact that two-thirds of the inconsistent users in our study had changed their bread spread type from plant stanol ester margarine to low-fat spread or soft margarine. On the other hand, a variety of other factors affect the bread spread choice of inconsistent users. In our study, 20% of the inconsistent users regarded taste as the main factor affecting bread spread choice, compared with only 3% among the consistent users.

In this study, the users of plant stanol ester margarine divided themselves into consistent and inconsistent users according to the follow-up question: 'What type of fat do you usually use on bread?' In fact, the question as such measures current bread spread choice and does not necessarily reveal the consistency of use, although the question was repeated after 1 or more years. Therefore, a validation was needed through the question on the type of bread spread during the past 5 years. According to this question, long-term use of plant stanol ester margarine was indeed more pronounced among consistent users compared with inconsistent users. This confirmed the validity of the approach.

Four consistent users reported that they have used plant stanol ester margarine only for 1 year. Because the time interval between completion of the two questionnaires ranged from 1.5 to 4.5 years, they probably used plant

stanol ester margarine by the times of the studies and during a 1-year period between the studies. The small number of such apparent discrepancies among the consistent users (four out of the total of 357) further shows that our repeated question concerning current bread spread choice is a relatively good indicator of long-term use.

Consistent users consumed on average 24 g of plant stanol ester margarine daily, which is considered optimal for lowering blood cholesterol^{5,7}. However, one-third of them consumed more than 25 g day⁻¹. Nearly one in four consistent users also reported the use of other plant stanol ester product in addition to the margarine. Health effects of high daily amounts of plant stanol ester are not known and need to be examined.

The follow-up study questionnaire was also sent to 3921 original non-users of plant stanol ester margarine to serve as a reference group for our users in our forthcoming studies. Original non-users who have become users will then be studied separately to elucidate the factors that lead to the use of plant stanol ester margarine.

Although the use of plant stanol ester margarine is more often inconsistent than consistent, there is nevertheless a relatively large subgroup of long-term users of plant stanol ester margarine. This new information is vital when the health effects, both beneficial and adverse, of long-term use of plant stanol ester margarine are assessed. In future,

we hope to address this issue by linking data from available health registries to the cohort of users of plant stanol ester margarine.

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